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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,263	12/02/2003	Noah E. Robinson		1262

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EXAMINER

LEARY, LOUISE N

ART UNIT PAPER NUMBER

1655

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/707,263	Applicant(s) ROBINSON, NOAH E.	
	Examiner Louise N. Leary	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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1. Claims 1-6 are pending in this application.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite because the claims have been presented as multiple sentences. Claims 1-6 are ambiguous because it is unclear if the intent was to present each step as a claim.

Claims 1-2 are indefinite because the phrase "The invention of" does not set forth a claim limitation. It is suggested that the phrase be deleted in each claim to comply with US Patent practice.

Claim 1 is indefinite because in lines 4-5, the phrase "atoms or groups or groups of atoms" is ambiguous and appears to contain a typographical error. It is suggested that "or groups" be deleted if the phrase contains a typographical error.

Claims 3, 4 and 5 provides for the use of "the techniques described in claims 1 and/or 2", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 3, 4 and 5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

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claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 3-5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Regarding claim 6, the phrase "As an example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Correction is required to particularly point out and distinctly claim the subject matter regarded as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(I). Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratton et al (J. of Pharmaceutical Sciences, Vol. 90, No. 12, pp 2141-2148, (December 2001).

Stratton et al disclose a technique for the design of changes in deamidation rates in a model peptide. Stratton et al describe "Controlling Deamidation Rates in a Model

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Peptide: Effects of Temperature, Peptide Concentration, and Additives". With respect to the claim limitation "the determination of a table of constants for atoms or groups or groups or groups of atoms", Stratton et al disclose the conformational effect and intramolecular event in the deamidation rate controlling method. See this entire reference. Also, Stratton et al disclose "[Deamidation of asparagines (Asn) residues is probably the most common pathway for chemical inactivation of protein pharmaceuticals^{1,2} The reaction rate for deamidation in aqueous solution is dependent on a number of extrinsic factors, such as pH,³⁻⁶ solvent dielectric,⁷ buffer concentration,⁵ and temperature,⁵ as well as intrinsic factors, such as the primary sequence⁸⁻¹⁰ and the presence of secondary^{2,11,12} and tertiary structure.^{13]}" See page 2141.

(II). Claim 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al (PNAS, Vol. 98, No. 8, pp 4367-4372, (April 2001).

Robinson et al disclose a technique for the design of changes in deamidation rates in a peptide sequences. Robinson et al disclose "Prediction of protein deamidation rates from primary and three-dimensional structure". The method quantitatively estimates "...deamidation of asparaginy (Asn) residues in proteins...". See the Abstract on page 4367. Regarding the instant "constants for atoms" table limitations, Robinson et al describe structural changes in proteins due to the effects of other molecular compounds. Also, Robinson et al describe hydrogen bonds associated with the proteins. See this entire document. Further, Robinson et al disclose "[Figs. 1-3 serve as a reasonable basis for estimating that Asn deamidation in proteins is, on

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average, determined approximately 60% by primary structure and 40% by 3D structure.]” Note page 4371.

(III). Claim 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson (PNAS, Vol. 99, No. 8, pp 5283-45288, (April 16, 2002).

Robinson discloses a technique for the design of changes in deamidation rates in a peptide sequences. Robinson discloses “Protein deamidation”.

rates from primary and three-dimensional structure”. The method quantitatively estimates “...deamidation of asparaginyl (Asn) residues in proteins...”. See the Abstract on page 5283. Regarding the instant “constants for atoms” table limitations, Robinson also describe structural changes in proteins due to the effects of other molecular compounds. Robinson et al describes atoms and hydrogen bonds associated with the proteins. See this entire document. In addition, Robinson et al disclose Asn deamidation in proteins and predicts the average determined by primary structure and by 3D structure. Note this entire document.

4. Darrington et al disclose “Effects of Insulin Concentration and Self-Association on the Partitioning of It’s a-21 Cyclic Anhydride Intermediate to Desamido Insulin and Covalent Dimer” and has been cited to further show the state of this art.

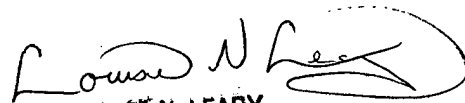
5. No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LOUISE N. LEARY
PRIMARY EXAMINER

February 2, 2006